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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. 2:15-MD-02641-DGC

THE PARTIES' SUBMISSION ON PLAINTIFFS' DISCOVERY REQUESTS REGARDING REPORTING ISSUES

In Case Management Order No. 10, Paragraph IV [Doc. 1319], the Court instructed the parties to discuss the specific discovery requests of Plaintiffs with respect to the reporting issues identified in the FDA warning letter. The parties have met and conferred regarding the additional discovery sought by Plaintiffs and reached agreement concerning many issues.

As directed by the Court, the parties submit this matrix addressing the remaining areas of disagreement:

GENERAL STATEMENT	
Plaintiffs' Position	**Defendants' Objection**
At the March 31, 2016, status conference, the Court concluded that the evidence relating to the FDA Warning Letter and Bard's under-reporting, non-reporting, and inaccurate reporting of problems with its IVC filters was clearly relevant to this case and virtually every claim in it. With the original 30(b)(6) deposition on the subject matter, Plaintiffs served a request for documents for 10 categories of documents. Following that deposition, and based on the testimony of Bard's designated witness, Plaintiffs served a second set of document requests seeking 27 specific categories of documents – most of which had been identified by Mr. Modra in the deposition. Prior to this Court's ruling on the discoverability of the FDA Warning Letter information, Bard served formal responses to some of the categories in the second set of document requests, indicating that it would be producing responsive documents to several of the categories. And, after entry of CMO 10, Bard agreed to produce documents in response to additional categories in the requests. Plaintiffs have not yet had opportunity to assess the responsiveness or completeness of those productions or the intended productions.	Consistent with the Court's direction in Case Management Order No. 10, Bard has produced – or agreed to produce – an extensive amount of information. Bard is presently scheduling the depositions of the three Field Assurance employees who report to Mr. Modra. Further, in response to Plaintiffs' 37 requests for production, Bard has already produced over 20,000 pages of documents related to the FDA Warning Letter. This production includes all correspondence to and from the FDA related to the Letter, as well as documents that reflect the various actions Bard took in response to the Letter. Additionally, Bard has produced or has agreed to produce voluminous standard operating procedures related to quality assurance and complaint handling, quality assurance and field assurance training materials, Bard's internal complaint tracking and trending materials, quality systems audits, failure mode effect analyses, corrective and preventative action plans, lists that reflect the documents reviewed by the FDA as part of its inspections, Bard's communications with two consultants who provided opinions that were shared with the FDA, and some documents related to divisional

After Bard's responses and the meet and confer between the parties, there remain essentially three issues: 1. Plaintiffs' requests for Bard's internal and external communications regarding the warning letter and reporting issues (Depo. requests 7 and 9, and RFP 35); 2. Plaintiffs' request for the employment files of four specific witnesses involved in these events (RFP 26); and 3. Defendants' refusal to produce the documents relating to Bard's dealings with the FDA from the three Bard executives to whom the FDA addressed its 483 letters and Warning Letter. Plaintiffs believe these requests are narrowly tailored to flesh out the ongoing issues concerning this critically important aspect of this case.	"management board" meetings during which the Letter was discussed. However, Bard believes a few of the Plaintiffs' requests are overly broad, and disproportionately burdensome

Request No. 7 (Plaintiffs' Notice of Deposition)

All internal communications relating to the subject matter of the warning letter issued by FDA on July 13, 2015.

Plaintiffs' Position	Defendants' Objection
Bard initially objected to this request as being overbroad because it sought "all" communications and contended that "the number of custodians whose ESI should be searched should be limited and targeted." Accordingly, Plaintiffs limited this request to communications involving a discrete set of 17 people. All but two of those people were identified by Mr. Modra at his deposition as being involved in the reporting issues, dealing with the FDA with respect to the Warning Letter, or were on other correspondence with the FDA relating to these issues. Thus, Plaintiffs significantly narrowed the scope in response to Bard's concerns. The subject matter of the request is, likewise, narrow as it relates precisely to the internal communications at Bard about the very issues that are the subject of the	Bard is amenable to providing additional, non-privileged, discovery as to internal communications relating to the FDA Warning Letter, within reasonable parameters. However, the plaintiffs' request for "all internal" communications is extraordinarily broad and, read literally, would require Bard to collect, process, and review ESI from every single employee who had any role -- no matter how non-substantive, minor, or duplicative of the role played by employees more centrally involved in the activities -- in addressing or responding to the Letter. Given the above, Bard believes that the number of custodians whose ESI should be searched should be limited and targeted.

FDA's warning letter.

Plaintiffs believe, as this Court stated in CMO 10, this information is clearly relevant and discoverable. After Plaintiffs limited this request to specific persons, Bard contended that it could not reasonably respond unless Plaintiffs provided "a list of key words or some specification of the search methodology" of Bard's ESI, claiming "it is impossible … to assess the burden" without Plaintiffs telling Bard how to search its ESI.

Plaintiffs proposed to work through the ESI search methodology as part of the parties' ongoing ESI discussions, but Bard insisted that Plaintiffs had to provide a *specific methodology for Bard to search ESI for this particular request*. Plaintiffs submit that contention is not reasonable.

This subject matter is not so unique as to require separate treatment for the search of ESI. Indeed, while Bard argues burdensomeness, it makes no showing of any undue burden. It has not disclosed the amount of ESI it would need to gather to respond to this request, the quantity of ESI that would need to be reviewed, or the time and cost it would take to do so. Nor does it provide any information from which

> "a party objecting to discovery must specifically demonstrate how the request is burdensome. *See Heraeus Kulzer, GmbH v. Biomet, Inc.*, 633 F.3d 591, 598 (7th Cir.2011); *Sauer v. Exelon Generation Co., No. 10 C 3258*, 2011 WL 3584780, at *5 (N.D.Ill. Aug.15, 2011). This specific showing can include 'an estimate of the number of documents that it would be required to provide ..., the number of hours of work by lawyers and paralegals required, [or] the expense.' *Heraeus Kulzer*, 633 F.3d at 598."

In the late afternoon of April 14th, the day before this submission was due, the plaintiffs for the first time provided the defendants with an ostensibly limited set of custodians for which they are seeking all communications. The list was extremely broad, including 17 separate custodians. Demonstrating that the plaintiffs had made no effort to focus their requests, the list included one employee who retired from the company before the FDA inspections even began, and another employee who has had no involvement whatsoever in the activities related to the warning letter.

Further, despite the defendants' inquiry, the plaintiffs declined to define what sort of search methodology they wanted undertaken for the ESI files of those 17 custodians they named at the eleventh hour. Contrary to the plaintiffs' contention, an understanding of the expected search methodology is essential for any assessment of the burden imposed by a request for ESI. In that regard, a request that targeted key words be applied to 8 custodians' files over a finite time period could easily be much less burdensome than the application of wide-ranging set of key words, without time frame restrictions, for a much smaller number of custodians.

In short, Bard cannot make a meaningful assessment as to the burden that would be associated with the plaintiffs' belated proposal, without some explanation as to what the plaintiffs' expect with such searches.

If the plaintiffs would specify a reasonable methodology, Bard believes that a targeted search of the ESI of Mr. Modra, the individual who spearheaded all of the company's efforts in response to the warning letter, and of the ESI of the three

Kleen Products LLC v. Packaging Corp. of Am., 2012 WL 4498465, at *15 (N.D.Ill., Sept. 28, 2012). Bard's request that Plaintiffs somehow come up with ESI search methodology for this specific request – without information as to the size, type, and contents of the ESI that would need to be searched (Bard has not even indicated what that is) – is a virtual impossibility. Plaintiffs are willing to work with Bard to come up with reasonable search methodology for all ESI, but they do not presently have the information from Bard to do so. All Plaintiffs request is that Bard conduct a reasonable search to produce responsive documents. To the extent that Bard believes that a search methodology needs to be determined to review this particular ESI, Plaintiffs believe Bard should use the methodology on which the parties ultimately agree (or the Court ultimately orders) for the searching of ESI.	Field Assurance employees who performed the retrospective analyses of the complaint reporting (Ms. Ludwig, Ms. Uebelacker and Mr. Wheeler) might be an appropriate starting point. After review of the communications of those central personnel, the plaintiffs would be in a position to make a reasoned determination of any additional communications necessary, rather than the expansive fishing expedition they are currently proposing. In sum, the plaintiffs' purported effort to narrow their request does not adequately address, much less resolve, the problems created by their extremely broad request.

Request No. 8 (Plaintiffs' Notice of Deposition)

Communication with FDA and internally since the issuance of the warning letter issued by FDA on July 13, 2015 which pertain to the subject matter and content of said warning letter.

Plaintiffs' Position	Defendants' Objection
Plaintiffs' position on this request is the same as with respect to Request No. 7 from the Notice of Deposition. Plaintiffs have voluntarily limited this request to the same 17 people identified by Mr. Modra at his deposition as being involved in the reporting issues, dealing with the FDA with respect to the Warning Letter, or who were on other correspondence with the FDA relating to these issues. These communications are clearly relevant under CMO 10.	Bard has already provided the plaintiffs with communications it had with FDA regarding the Warning Letter. Bard is amenable to providing additional, non-privileged, discovery as to internal communications relating to the FDA Warning Letter, within reasonable parameters. However, the plaintiff request for "all internal" communications is extraordinarily broad and, read literally, would require Bard to collect, process, and

Plaintiffs have asked that Bard conduct a reasonable search to produce responsive documents in accordance with the ESI search methodology on which the parties ultimately agree (or the Court ultimately orders). Bard has refused and insists that Plaintiffs come up with a specific search methodology for these specific documents – even though Bard has disclosed nothing as to the location, type, or quantity of records that are to be searched. Plaintiffs request that Bard conduct a reasonable search to produce responsive documents. To the extent that Bard believes that a search methodology needs to be determined to review this particular ESI, Plaintiffs believe Bard should use the methodology on which the parties ultimately agree (or the Court ultimately orders) for the searching of ESI.	review ESI from every single employee who had any role, no matter how non-substantive or minor -- in addressing or responding to the Letter. Given the above, Bard believes that the number of custodians whose ESI should be searched should be limited and targeted. For the reasons set forth above, the defendants do not believe the plaintiffs' eleventh hour listing of 17 custodians, whose ESI they want searched via some unspecified methodology, accomplishes that.

Request for Production No. 26

The complete employment files at Bard for:

a. Chad Modra,

b. Maureen Uebelocker,

c. John Wheeler, and

d. Judy Ludwig.

Plaintiffs' Position	**Defendants' Objection**
Plaintiffs have requested the employment files of four people directly involved in the response to the FDA warning letter and the under- and non-reporting of adverse events. Discovery of employment files is permissible if "(1) the material sought is 'clearly relevant,' and (2) the need for discovery is compelling because the information sought is not otherwise readily obtainable." *In re Sunrise Securities Litigation*, 130 F.R.D. 560, 580 (E.D. Pa. 1989) (*cited by Barbara et al. v. Davol Inc. and C.R. Bard, Inc*, C.A. No. 07-5058).	The defendants object to the request for employee personnel files, both because of the privacy interests implicated and because the burden and expense of producing those files outweigh the relevance (if any). See In re: C. R. Bard, Inc. Pelvic Repair Systems Product Liability Litigation, MDL No. 2187, Dkt. No. 1175, (S.D.W.Va. October 31, 2014) (order denying motion to compel) ("From the standpoint of proportionality, Plaintiffs' motion should be denied for the simple reason that the burden and expense to Bard of the proposed

Relevant portions of an employee's personnel file are also discoverable when an employee's actions or inactions had a direct bearing on the issues in dispute. *United States EEOC v. McCormick & Schmick's Seafood Rests.*, No. DKC–11–2695, 2012 WL 3563877, at *4 (D.Md. Aug. 16, 2012). While Bard relies on orders in other MDLs for the proposition that employment files are not discoverable, the plaintiffs in those matters sought production of *all* personnel files. The courts were clear, however, that limited and focused requests for employment files were not precluded. For example, the Court in MDL No. 2187 specifically stated that its ruling "is not to say that Plaintiffs' may never be able to present compelling reasons for the production of a *specific* employee's personnel file. There may [be] a particular employee who played a unique role in this case, or whose actions or inactions are especially relevant to a certain claim or defense. In that case, Plaintiffs are free to serve Bard with a request for production of documents . . . and to follow up with a motion to compel, if necessary." Here, Plaintiffs seek the production of personnel files for four employees. Mr. Modra was responsible for the Quality Assurance at Bard during the period of the dramatic under- and non-reporting of adverse events of which this court is already aware. The other three employees all directly reported to Mr. Modra during that time period. Additionally, Mr. Modra was responsible for responding on behalf of Bard to the FDA on the Warning Letter. Thus, these witnesses were directly involved in these core issues. What actions Bard took as to their employment as a result of their involvement in the failures is clearly relevant and discoverable. Demotions, reprimands, or adverse consequences to these employees	discovery outweigh the anticipated benefits to Plaintiffs."); see also In re: Xarelto (Rivaroxaban) Products Liability Litigation, No. MDL 2592, 2016 WL 311762, ____ F.R.D. _____ (E.D. La. Jan. 26, 2016) (order addressing discoverability of employee personnel files) (rejecting blanket request for personnel files, absent a particularized showing of need). Bard does not disagree with the proposition advanced by the plaintiffs, that the production of a specific employee's file may be appropriate in particularized circumstances. Here, however, the plaintiffs have not—and cannot—make such a showing. Nor do the plaintiffs acknowledge the well-recognized privacy interests that counsel against the production of such files, absent a very particularized showing. In this situation, those interests outweigh the plaintiffs' vague claim of need simply because the employees in question were involved in responding to the FDA warning letter.

based on the dramatic reporting failures would clearly be relevant. And, Bard cannot seriously contend that production of four employee files from the personnel office is unduly burdensome. To the extent that the employee files contain sensitive private health information of financial information, Plaintiffs would be agreeable to production of this material subject to the Protective Order entered in this case or limited redaction of the medical/financial information.	

Request for Production No. 35

All internal communications (including all emails) of Bard employees and agents regarding the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C. R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C. R. Bard, dated July 13, 2015, or Bard's responses thereto. This request specifically includes but is not limited to all communications regarding the retrospective review of IVC filter complaint records and the reclassification of reportability status for such records.

Plaintiffs' Position	**Defendants' Objection**
Plaintiffs' position on this issue is the same as with respect to Requests number 7 and 8 to the Notice of Deposition. Plaintiffs have voluntarily limited this request to the same people identified by Mr. Modra at his deposition as being involved in the reporting issues, dealing with the FDA with respect to the Warning Letter, or who were on other correspondence with the FDA relating to these issues. The subject matter of the communications is clearly relevant under CMO 10, and the scope of the request is appropriate and reasonable. Plaintiffs ask that Bard conduct a reasonable search to produce responsive	Bard is amenable to providing additional, non-privileged, discovery as to internal communications relating to the FDA Warning Letter, within reasonable parameters. However, the plaintiff request for "all internal" communications is extraordinarily broad and, read literally, would require Bard to collect, process, and review ESI from every single employee who had any role, no matter how non-substantive or minor -- in addressing or responding to the Letter. Given the above, Bard believes that the number of custodians whose ESI should be

documents in accordance with the ESI search methodology on which the parties ultimately agree (or the Court ultimately orders). Bard has refused and insists that Plaintiffs come up with a specific search methodology for these specific documents – even though Bard has disclosed nothing as to the location, type, or quantity of records that are to be searched. Plaintiffs request that Bard conduct a reasonable search to produce responsive documents. To the extent that Bard believes that a search methodology needs to be determined to review this particular ESI, Plaintiffs believe Bard should use the methodology on which the parties ultimately agree (or the Court ultimately orders) for the searching of ESI.	searched should be limited and targeted. Bard also believes the plaintiffs' belated list of 17 custodians, whose ESI they want searched according to some unspecified methodology, does not accomplish that.

E-mail Request For "the files of Ring, Williamson, and Gaede."

Plaintiffs' Position	Defendants' Objection
Messrs. Ring, Williamson, and Gaede were all named recipients of the 483 letters and Warning Letter from the FDA that included the FDA's findings that Bard failed to accurately report adverse events relating to Bard's IVC filters. Mr. Williamson and Mr. Gaede were the signatories of several letters to the FDA in response to the FDA's letters. In order to determine the involvement of these individuals in Bard's dealing with the FDA with respect to the 483 letters, the Warning Letter, and the issues raised in them, Plaintiffs have asked for the production of their files relating to those issues. Bard's entire objection is premised on the contention that Plaintiffs must accept Mr. Modra's testimony that he authored the letters in quest. Regardless of the testimony of Bard's corporate witness, the fact that they are recipients and authors of the very	Without any definition of the scope of their request, the Plaintiffs have informally requested the "files" of three executives including Tim Ring, the Chairman and Chief Executive Officer of C. R. Bard, Inc. The other two executives identified by the Plaintiffs are Jason Gaede, the Vice President, Plant Operations at Bard's Glens Falls Technology Center (the site where filters are manufactured); and Steve Williamson, the President of Bard Peripheral Vascular, Inc. The plaintiffs have obviously identified those individuals simply because their names appear on several official communications. The actual warning letter was addressed to Mr. Ring, in his capacity as C.E.O. of the company, as the FDA's practice is to address a warning letter to the highest known official at a company. Various response letters to the FDA bear the signatures of Messrs. Gaede and

letters at issue suggests they have knowledge and information about these letters and the issues in them. Indeed, Bard does not even attempt to argue that the evidence is not relevant or that they had no involvement whatsoever – something that can only be proven by production of their files. Rather than proceed directly to deposition, Plaintiffs have asked for the relevant files of these witnesses to determine their involvement. That request is reasonable, and this Court should order Bard to produce the documents from these witnesses relating to the FDA and the under- and non-reporting issues.	Williamson. However, as Mr. Modra has testified, he and his department prepared those letters for the executives' signatures. In short, there is no basis for the fishing expedition proposed by the Plaintiffs, with their demand that Bard produce the "files" (a term not defined) for three senior executives, merely because their names were listed on official correspondence to or from the agency. That is particularly true when the extensive testimony of the employee responsible for handling the issues in no way implicated the executives in any substantive dealings with the issues or the FDA.

DATED this 15th day of April 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of April, 2016, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Deborah Yanazzo
Deborah Yanazzo